(*Toxocara cati* and *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme* and *Uncinaria stenocephala*).

(5) Dichlorvos is a cholinesterase inhibitor. Do not use simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(6) Do not use in animals under 10 days of age or 1 pound of body weight.

(7) Do not administer to animals showing signs of constipation, mechanical blockage of the intestinal tract, impaired liver function, or recently exposed to or showing signs of infectious disease.

(8) Do not use in dogs or puppies infected with *Dirofilaria immitis*.

(9) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 1, 1999.

Andrew J. Beaulieu,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–9459 Filed 4–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of sulfadimethoxine (SDM) soluble powder to make a medicated drinking water for the treatment of chickens and turkeys and to make a drinking water or drench for treatment of dairy calves and heifers and beef cattle.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–258 that provides for use of SDM soluble powder in drinking water for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza in broiler and replacement chickens; and coccidiosis and fowl cholera in meat-producing turkeys. The ANADA also provides for use of SDM soluble powder in drinking water or as a drench for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine, and for calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine, in dairy calves, dairy heifers, and beef cattle.

ANADA 200–258 is approved as a generic copy of Pfizer's NADA 46–285 Albon® (sulfadimethoxine soluble powder). ANADA 200–258 is approved as of March 4, 1999, and the regulations in 21 CFR 520.2220a(a)(2) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2220a [Amended]

2. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (a)(2) by removing ''and 057561'' and adding in its place ''057561, and 059130''.

Dated: April 1, 1999.

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–9456 Filed 4–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Omeprazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merial Ltd. The NADA provides for oral use of omeprazole for the treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed NADA 141–123 that provides for oral, veterinary prescription use of GastroGard® (omeprazole) oral paste for horses and foals 4 weeks of age and older for the treatment and prevention of recurrence of gastric ulcers. The NADA is approved as of March 16, 1999, and the regulations are amended by adding 21 CFR 520.1615 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512 of the Federal, Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 16, 1999, because no active ingredient